

REMARKS

The present application is directed to compositions and methods involving therapeutic delivery compounds. The compounds are particularly suited for the effective delivery of genetic matter and other compounds to the interior of cells. Claims 1-4, 6-7, 9-12, 14-15, and 17-34 were pending prior to the issuance of the July 28, 2004, Office Action. Following entry of this amendment claims 1-4, 6-7, 9-12, 14-15 and 18-19, 21-25, 27-42 will be pending. Claims 1, 9, 12, 19, 21-25, 32 and 34 are amended and Claims 5, 8, 13, 16-17, 20, and 26 have been cancelled. New Claims 35-42 have been added. No new matter is added and support for the amendments is found throughout the specification.

Drawings

In the July 28, 2004 Non-Final Office Action, the Examiner objected to the drawings filed on July 28, 2000. Applicants respectfully enclose four replacement sheets for Figures 1-4 in which the margins are corrected. In addition, applicants have attempted to improve the tone quality of Figure 4.

Claim rejections under 35 U.S.C. § 112, second paragraph

In the July 28, 2004 Office Action, the Examiner rejected claims 1-4, 6-12, 14-31 and 34 under 35 U.S.C. §112, second paragraph, as indefinite on the basis that the intended scope of the nucleic acids to be embraced was unclear because the claims included both expression vectors and oligonucleotides. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 1, 9 and 34 have been amended to specify that the nucleic acid molecule is an oligonucleotide by deleting the term “expression vector”. Applicants submit that the amended claims clearly define the nucleic acid molecules. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph..

Claim rejections under 35 U.S.C. § 112, first paragraph

In the July 28, 2004 Office Action, the Examiner rejected claims 1, 6, 7, 9, 14, 15 and 17-34 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner stated that the phrase “less than 45% of the total weight of the block copolymer” could be interpreted as being a range from 0 to 45%. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 1, 9, 25 and 34 have been amended to specify a minimum weight range of 1%. Support for this minimum weight can be found on page 14, line 33 of the present specification. In addition, Applicants direct the Examiner to page 15, lines 30-34, of the present application where Applicants state, “It should be understood that the molecular weight and percentage ranges that are described for the block copolymer are to be considered outside ranges and that any population of molecules that falls within the stated ranges is considered an embodiment of the present invention.” (emphasis added) Applicants respectfully submit that for the above reasons they have overcome the Examiner’s rejection of claims 1, 6, 7, 9, 14 15 and 17-34 under §112, first paragraph, and request its withdrawal.

The Examiner also rejected claims 32 and 33 for failing to comply with the written description requirement. The Examiner concluded that no copolymers of less than 750 Daltons were provided. Applicants respectfully traverse.

The copolymer CRL-1187 (having a weight of approximately 750 Da) can be found in Table 2 (on page 17 of the present specification). Moreover, the term “approximately” is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). Accordingly, Applicants request withdrawal of the Examiner rejection of claims 32 and 33 under §112, first paragraph.

The Examiner also rejected claim 33 for failing to comply with the written description requirement. The Examiner concluded that a block copolymer having a polyoxyethylene portion of “approximately 10%-30% of the total weight of the block copolymer” was not supported by written description. Applicants respectfully traverse.

Copolymers having a polyoxyethylene portion of approximately 10%-30% of the total weight of the block copolymer can be found in Table 2 (on page 17 of the present specification) and include copolymers such as CRL-1183 (~10%), CRL-1122 (~12%), CRL-9352 (~15%), CRL-1187 (~25%), CRL-8143 (~30%). In addition, the term “approximately” is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). Accordingly, Applicants request withdrawal of the Examiner’s rejection under §112, first paragraph.

The Examiner also rejected claim 34 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxypropylene portion “between approximately 4400 and 15,000 Daltons” was not supported by written description. Applicants respectfully traverse.

Copolymers having a polyoxypropylene portion of approximately 4400 and 15,000 Daltons, such as copolymers CRL-8941 (~4400), CRL-3632 (~4740), CRL-1122 (~5900), CRL-1235 (~7500), CRL-1190 (~10000), CRL-336 (~14,000) can be found in Table 2 (page 17 of the present specification). Moreover, the term “approximately” is defined within the specification to mean the stated concentration plus or minus ten percent (see page 13, lines 21-23 of the present specification). Accordingly, Applicants request withdrawal of the Examiner’s rejection under §112, first paragraph.

Claim rejections under 35 U.S.C. § 102

In the July 28, 2004 Office Action, the Examiner rejected claims 1-4, 9-12, 17, 19 and 20 as anticipated by Allison et al., U.S. 5,376,369 (hereinafter “Allison et al.”) under 35 U.S.C. §102(b). The Examiner stated that Allison et al. teach that Pluronics L101, L121 and L122 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines, and that an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are capable of expressing their own genes. Applicants respectfully submit that the amendments to the claims overcome the rejection.

As mentioned above, claims 1, 9 and 34 have been amended to delete the term “expression vector”. Therefore the rejection is now moot. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims under 35 U.S.C. §102(b).

In the July 28, 2004 Office Action, the Examiner rejected claims 1-3, 9-11, 17 and 19-21 as being anticipated under 35 U.S.C. § 102(e) by Wasmoen et al., U.S. 5,656,275 (hereinafter “Wasmoen et al.”) as evidenced by Osorio et al., WO 99/39733 (hereinafter “Osorio et al.”). The Examiner stated that Wasmoen et al. teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that an expression vector capable of expressing genes is anticipated by viruses, which are capable of expressing their own genes. Applicants respectfully submit that the amendments to the claims overcome the rejection.

As mentioned above, claims 1, 9 and 34 have been amended to delete the term “expression vector”, and the rejection is now moot. Accordingly, Applicants believe they have overcome the Examiner’s rejection under 35 U.S.C. 102(e) and request its withdrawal.

Claim rejections under 35 U.S.C. § 103

In the July 28, 2004 Office Action, the Examiner rejected claims 1, 6-7, 9, 14-15 and 34 as being unpatentable under 35 U.S.C. § 103(a) over Wasmoen et al. in view of Miyamura et al. U.S. 5,372,928 (hereinafter “Miyamura et al.”). The Examiner stated that Wasmoen et al. teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that whole viruses could be considered expression vectors. Applicants respectfully submit that the amendments to the claims overcome the rejection.

As mentioned above, claims 1, 9 and 34 have been amended to delete the term “expression vector”. In addition, the deficiencies of Wasmoen et al. are not satisfied by Miyamura et al. Applicants unexpectedly discovered that the claimed block facilitate the transport of DNA and other compounds into cells and are thus useful in the intracellular delivery of therapeutic agents *in vivo* for the treatment of disease. Miyamura et al. do not disclose or suggest this discovery. Accordingly, for at least the above reasons, Applicants assert that claims

1, 6-7, 9, 14-15 and 34 are non-obvious and request withdrawal of the Examiner's rejection under 35 U.S.C. §103(a).

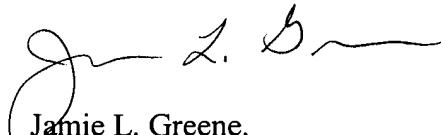
CONCLUSION

The foregoing is submitted as a full and complete Response to the Office Action mailed on July 28, 2004. For at least the reasons given above, Applicants respectfully submit that the pending claims are definite, novel and non-obvious. Accordingly, Applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited.

A check for additional claims is enclosed. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

The Examiner is invited and encouraged to contact the undersigned attorney of record at 404-745-2473 or the telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,



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